UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	:	**3:09-md-02100-DRH-PMF**
	:	**MDL No. 2100**
	:	Judge David R. Herndon
This Document Applies To All Actions	:	

ALL CASES

CASE MANAGEMENT ORDER NUMBER 35

Regarding the Production of Witnesses for Deposition

I. INTRODUCTION

A dispute has arisen between the parties with respect to the fact witness depositions of two corporate executives, Dr. Gunnar Riemann (executive with Bayer CropScience and former member of Bayer Schering Pharma AG's (now known as Bayer AG) Board of Management) and Mark Trudeau (executive with Bayer Healthcare Pharmaceuticals Inc. and Bayer HealthCare LLC USA). A dispute has also arisen with regard to the fact witness deposition and custodial files of Guus van der Werff, a Dutch national employed by a Dutch entity (Bayer B.V.) that is not a party to this litigation or a subsidiary of any of the named defendants.

Plaintiffs have asked the Court to order defendants to produce these witnesses for deposition and/or impose penalties if the witnesses are not produced. Defendants, Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer"),have asked the Court to enter a protective order barring the depositions of all three witnesses. The Court addresses the disputes with regard to each witness below.

II. ANALYSIS

A. Relevant Legal Principles

District courts have broad discretion in matters relating to discovery. *Patterson v. Avery Dennison Corp*., 281 F.3d 676, 681 (7th Cir. 2002); *Packman v. Chicago Tribune Co*., 267 F.3d 628, 646-47 (7th Cir.2001); *Rennie v. Dalton*, 3 F.3d 1100, 1110 (7th Cir.1993). Although there is a strong public policy in favor of disclosure of relevant materials, Rule 26(b)(2) of the Federal Rules of Civil Procedure empowers district courts to limit the scope of discovery if "the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive."*Patterson*, 281 F.3d at 681. "Before restricting discovery, the court should consider "the totality of the circumstances, weighing the value of the material sought against the burden of providing it, and taking into account society's interest in furthering the truthseeking function in the particular case before the court." *Id*. (internal citation omitted).

When assessing discovery requests that (1) will be effected in a foreign country and (2) give rise to conflicts between U.S. discovery law and foreign law, courts must consider the principles discussed by the Supreme Court in *SocieteNationaleIndustrielle Aerospatiale v. United States District Court for the Southern District of Iowa*, 482 U.S. 522, 107 S.Ct. 2542, 96 L.Ed. 2d 461 (1987). In *Aerospatiale*, the Supreme Court provided guidance with regard to how courts should resolve conflicts that arise when discovery requests implicate both U.S. discovery rules and the Hague Convention's Procedures on Taking Evidence. The Supreme Court concluded that district courts have complete discretion in resolving conflicts presented between the application of the Federal Rules of Discovery and the Hague convention. *See Aerospatiale,* 482 U.S. at 539-540 ("Hague Convention did not deprive the District Court of the jurisdiction it otherwise possessed to order a foreign national party before it to produce evidence physically located within a signatory nation"). Thus, Hague Convention procedures are not mandatory.

However, the Supreme Court also cautioned that, in accord with the principle of comity between sovereign nations, under certain circumstances, a district court should give deference to the laws of a foreign sovereign. See *Aerospatiale,* 482 U.S. 522, 543 n. 27(1987).*See also Id.* at 546("American courts should...take care to demonstrate due respect for any special problem confronted by the foreign litigant on account of its nationality or the location of its operations, and for any sovereign interest expressed by a foreign state."); *Id*.

(American courts should exercise "special vigilance to protect the foreign litigants from the danger that unnecessary, or unduly burdensome discovery may place them in a disadvantageous position." *Aerospaitale v. United States District Court*, 482 U.S. 522, 546 (1987).

With regard to depositions of non-employees, the Court is not aware of any authority supporting the contention that a corporate defendant can be compelled to produce a non-employee for a deposition. *See e.g., In re Ski Train Fire of November 11, 2000 Kaprun Austria,* MDL 1428, 2006 WL 1328259, at *9 (S.D.N.Y. May 16, 2006) (Katz, M.J.) ("There is simply no authority for the proposition that a corporate party must produce for deposition fact witnesses who are not employed by, and do not speak for, that party."). The Court also notes that ordering an entity to produce a non-employee seems particularly problematic when the witness is not a U.S. citizen and is employed by a foreign entity that does not manufacture or sell its products in the United States. *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846 (2011) (foreign subsidiary that does not manufacture or sell its products in the United States is not subject to personal jurisdiction).

Finally, after considering the totality of the circumstances, district courts may preclude the depositions of high-ranking executives if the witness does not possess unique or specialized knowledge relevant to the litigation. *See Patterson v. Amery Dennison Corp.*, 281 F.3d 676, 681-82 (7th Cir. 2002) (upholding district court's refusal to compel high-ranking executive's deposition

and noting that plaintiff's failure to submit any interrogatories suggested that the executive did not possess information that was more than "marginally relevant"); *Craig &Landreth, Inc. v. Mazda Motor of Am., Inc.*, 4:07-cv-134-SEB-WGH, 2009 WL 103650, at *2 (S.D. Ind. Jan. 12, 2009) (Hussman, Jr. J.) (declining to compel deposition of high-ranking corporate official absent showing of direct knowledge relevant to the case and exhaustion of other less burdensome avenues for obtaining information).

B. Requested Deposition and Custodial Files of Guss van der Werff

1. Background

Mr. van der Werff is a resident and citizen of the Netherlands who serves as the Head of Regulatory Affairs for Bayer B.V., a Dutch company that is not a defendant in this litigation and is not a subsidiary of Bayer Pharma AG.[1]Def. July 15, 2011 Letter from John E. Galvin to the Court ("Def. Letter"), p. 3. Bayer B.V. is a wholly owned subsidiary of Bayer Hispania, S.L., a Spanish corporation. Doc. 1883 p. 2 n.1.Bayer Hispania, S.L., in turn, is a wholly owned subsidiary of Bayer AG. *Id*. Bayer B.V. does not manufacture Yasmin or Yaz, or market the medicines in the United States. *Id*. at p. 2.As the Head of Regulatory Affairs for Bayer B.V., Mr. van der Werff is Bayer's formal liaison with the Dutch regulatory

[1] Plaintiffs' initial letter to the Court asserts that Mr. van der Werff works in "Bayer's Global Regulatory Affairs Department." Pl. Letter p. 2. Bayer's letter in response asserts that Mr. van der Werff is in fact an employee of Bayer B.V. Def. Letter pp. 1 & 3.Plaintiffs responsive pleading does not contest this assertion and acknowledges that Mr. van der Werff is an employee of Bayer B.V. – a "separate, nonparty Dutch company." Doc. 1883 p. 2.

authority with regard to Bayer's drospirenone-containing combined oral contraceptives.[2]

Plaintiffs maintain that Mr. van der Werff was and is intimately involved with highly important foreign regulatory matters regarding Bayer's drospirenone-containing combined oral contraceptives. Plaintiffs contend that Mr. van der Werff's interactions with foreign regulatory authorities make him an instrumental fact witness and seek to depose him in that regard.[3]Bayer disagrees, arguing that Mr. van der Werff's testimony would be duplicative and unreasonably burdensome, and therefore the Court should enter a protective order barring plaintiffs from seeking Mr. van der Werff's deposition. *See* Def. Letter pp. 10-13; Doc. 1883 pp. 4-7. Specifically, Bayer argues that (1) plaintiffs are already receiving relevant portions of the European Union contact report database;(2)

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[2] Bayer provides the following pertinent explanation of the relevant procedure for approving prescription pharmaceuticals in the European Union:

> In the European Union, a prescription pharmaceutical may be approved through the Mutual Recognition Procedure. Under the Mutual Recognition Procedure, one country performs the initial regulatory review on a prescription pharmaceutical; that country is the "reference member state" for that medicine. Regulatory authorities in other European Union countries then consider (and often recognize) the approval from the "reference member state" in conjunction with their review of the prescription pharmaceutical. The Netherlands is the "reference member state" for Bayer's drospirenone-containing combined oral contraceptives.

Def. Letter p. 3 n.4.

[3] Specifically mentioned regulatory authorities include the following: the Medicines Evaluation Board ("MEB") and the Pharmacovigilance Working Party of the European Union ("PhVWP").

plaintiffs have had and will have the opportunity to depose a number of Bayer Pharma AG witnesses with full knowledge of regulatory proceedings in Europe; and (3) foreign regulatory matters have no bearing on Bayer's liability under American law.

Separate and aside from the argument that Mr. van der Werff's testimony would be duplicative and unduly burdensome, is the issue of whether Mr. van der Werff – a Dutch national, working in the Netherlands for a Dutch entity that is not a party to this litigation and is not a subsidiary of Bayer Pharma A.G. – can be compelled to testify. This issue has arisen because Mr. van der Werffhas stated he will not voluntarily appear for a deposition. Def. Letter p. 10; Doc. 1883 p. 2. Bayer contends that, as a matter of Dutch labor law, neither Bayer nor Mr. van der Werff's employer – Bayer B.V. – can compel Mr. van der Werff to testify.Because Mr. van der Werff cannot be compelled to testify under Dutch law, Bayer argues that ordering him to testify would violate principles of comity. Def. Letter pp. 13-14; Doc. 1883 pp. 3-4.

Plaintiffs do not contest Bayer's assertions with regard to Dutch labor law. Instead, they focus on (1) whether Mr. van der Werff's testimony would be duplicative and/or unduly burdensome under U.S. Discovery law and (2) whether Mr. van der Werff can be compelled to testify under U.S. Discovery law. Plaintiffs contend that if Bayer Pharma AG does not produce Mr. van der Werff they will seek a preclusive order, a curative jury instruction, and/or sue Bayer B.V.

2. Analysis

After reviewing the parties' arguments and supporting documentation, the Court concludes that Mr. van der Werff possesses information about foreign regulatory issues that is relevant to this litigation. If the Court did not have to consider Dutch labor law, as well as the employment relationship (or lack thereof) between Mr. van der Werff and Bayer Pharma AG, it would have no problem ordering Mr. van der Werff to appear for a deposition. But that is not the hand that has been dealt. Considering the totality of the circumstances, weighing the value of the material sought against the burden of providing it, and taking into account principles of comity and the duplicative nature of the testimony sought, the Court will not order Bayer to produce Mr. van der Werff for the requested deposition.

As noted, Mr. van der Werff works for Bayer B.V. – a Dutch company that is not a subsidiary of Bayer Pharma A.G. or any other defendant in this litigation. Thus, Mr. van der Werff is a non-employee witness. The Court is not satisfied that Bayer Pharma A.G (or any of the named defendants) is in a position to compel Mr. van der Werff to testify. Plaintiffs do not contest Mr. van der Werff's employment status. Instead, they argue that Mr. van der Werff's in depth interactions with foreign regulatory authorities undermines any contention that he is not under the control of any defendant in this litigation. The Court finds this argument unconvincing; Mr. van der Werff's involvement in foreign regulatory

affairs does not change the fact that he is a non-employee witness and is not under the control of Bayer.

In addition, Mr. van der Werff is a Dutch national, working in the Netherlands, for a Dutch company. Therefore, the Court must consider whether ordering Mr. van der Werff to appear for a U.S.-style deposition would conflict with Dutch law. Bayer provides the following pertinent information with regard to Dutch law:

- Pursuant to Article 7:611 of the Dutch Civil Code, employees may be sanctioned by their employer if they fail to act as a "good employee." To be a "good employee," the employee must comply with "reasonable" requests from the employer.

- Under Dutch law, a civil party cannot force another civil party to appear for a deposition, other than through a court procedure.

- A Dutch court would likely conclude that appearing for the requested U.S.-style deposition is not within the scope of Mr. van der Werff's employment – particularly when Bayer B.V. is not a party to this litigation and is not a subsidiary of Bayer Pharma AG.

- A Dutch court would likely conclude that a request from Mr. van der Werff's employer to appear for a U.S.-style deposition is not "reasonable" and that refusing to comply with such a request does not constitute a failure to act as a "good employee." Therefore, naming Bayer B.V. as a

defendant would not allow Bayer B.V. to compel Mr. van der Werff's appearance for the requested deposition.

See Def. Letter Exhibit 1(Declaration of Rob van Eldik); Doc. 1883-1 (Supplemental Declaration of Rob van Eldik). Considering Bayer's assertions with regard to Dutch law as well as plaintiffs' failure to dispute the same, the Court is convinced that under Dutch law Mr. van der Werff is beyond the control of Bayer and of his employer Bayer B.V. Thus, ordering Bayer to produce Mr. van der Werff for the requested deposition would not only be fruitless, it would also give rise to a potential conflict with Dutch law.

The Court also notes that the plaintiffs have deposed and will depose several other witnesses who are well versed on foreign regulatory affairs. *See* Def. Letter pp. 10-13; Doc. 1877 p. 3. A number of these witnesses even accompanied Mr. van der Werff to regulatory meetings. *See e.g.*,Doc. 1883-3 (seven Bayer representatives attended the December 2009 PhVWP meeting). Thus, much of the testimony plaintiffs hope to elicit from Mr. van der Werff would be duplicative. Moreover, there is nothing in the record to suggest that others have deferred to Mr. van der Werff for information pertaining to the subject at issue. In fact, one witness, Dr. Fiedler, testified in her deposition that she "wondered whether [Mr. van der Werff] really understood the discussion [regarding the European label change] and what the discussion was all about." *See* Doc. 1883-2 (Fiedler Dep.) at 645:17-646:16, 649:1-16.

In summary, the Court finds that Mr. van der Werff is beyond the control of Bayer and, under Dutch law, is likely beyond the control of his employer Bayer B.V. In addition, the Court finds that much of the information sought is duplicative and available through other less intrusive means. In light of these findings, balancing the value of the information sought and the burden of producing it, as well as the comity implications, the Court will not require the production of Mr. van der Werff for the requested deposition. Further, for reasons already discussed, the Court is also denying plaintiffs' request for a preclusive order or a curative jury instruction with regard to Mr. van der Werff.

If plaintiffs have other means of compelling Mr. van der Werff to appear for a deposition (such as a request under the Hague Convention), they may pursue those means. However, considering the duplicative nature of the testimony that is being sought, the time it takes to pursue Mr. van der Werff's deposition via such alternative means shall not be grounds for a continuance of any deadlines.

Finally, with regard to the production of Mr. van der Werff's custodial files, the Court agrees that plaintiffs' request, which only pertains to those documents in his custodial file which relate to his interactions with MEB and PhVWP with regard to Bayer's drospirenone-containing medicines, does not improperly expand the scope of foreign regulatory discovery. Accordingly, to the extent that Bayer has the ability to obtain copies of the requested records, they shall be produced.

C. Requested Depositions of Dr. Gunnar Riemann and Mark Trudeau

1. Background

Dr. Riemann is the President of the Environmental Science Division of Bayer CropScience and a member of the Bayer CropScience Executive Committee. Def. Letter Exhibit A ¶ 2. From September 2006 to June 2009, Dr. Riemann was a member of Bayer Schering Pharma AG's Board of Management in Germany. *Id*. He had oversight of the Women's Healthcare business unit from May 2008 until June 2009, during which time he also had oversight over a number of additional Bayer business units. *Id*.

Plaintiffs contend, without support, that Dr. Riemann served on a special DRSP Task Force. Pl. Letter at 5. Bayer has provided a declaration from Dr. Riemann stating that he did not serve on this Task Force. Def. Letter Exhibit A ¶ 4.S*ee also* Def. Letter Exhibit B (DRSP Task Force Meeting Minutes which do not list Dr. Riemann as a member of the Task Force). Plaintiff additionally asserts that Mr. Trudeau "was involved with the company focus on the financial implications of the DRSP product market share." Pl. Letter p. 5. However, Mr. Riemann's declaration indicates that he was not personally involved in U.S. regulatory decision-making. Def. Letter Exhibit A ¶ 4.

Mr. Trudeau is the President and Chief Executive Officer of Bayer Healthcare Pharmaceuticals Inc. and Bayer HealthCare LLC USA, and has been employed by Bayer since 2009. Def. Letter Exhibit C ¶ 2.From January to August

2010, Mr. Trudeau was the interim President of Bayer's Global Specialty Medicine Business Unit. *Id.*

While Mr. Trudeau and Dr. Riemann admit that they have overarching business responsibilities that encompass (or encompassed) YAZ and Yasmin, they deny that they have been involved in day-to-day decision-making that would provide them with unique knowledge relevant to this litigation. Def. Letter Ex. A ¶¶ 3-5; Def. Letter Ex. C ¶¶ 4-5.

Plaintiffs disagree, asserting that Dr. Riemann and Mr. Trudeau possess unique information that is relevant to this litigation and is not available from other sources. Pl. Letter pp. 4-5. Plaintiffs, however, have only provided general conclusory statements about the witnesses' alleged knowledge. *See e.g.*, Pl. Letter p. 5 (Dr. Riemann's name appears on more than 115,000 documents); *Id.* ("ultimate decisions and visions were surely promulgated by these two witnesses"); Doc. 1877 p. 13 (asserting unique knowledge based on "their responsibility for ultimate decisions regarding extremely relevant issues in this litigation"); Doc. 1877 p. 13 (the "ultimate decisions regarding DRSPproducts. . . are essentially the unique and personal knowledge of Mr. Trudeau and Dr. Riemann").

The documents referenced by the plaintiffs are also not helpful. Plaintiffs list six emails or email chains in which Dr. Riemann appears and five documents in which Mr. Trudeau appears as evidence of the witnesses'

specialized or unique knowledge. However, none of the emails demonstrate unique or specialized knowledge on the part of these witnesses. The referenced documents do not indicate that either executive was included as a first line scientist, investigator, marketer, or regulation lobbyist. Instead, the emails simply indicate an effort to keep Mr. Trudeau and Dr. Riemann "in the loop."

In addition, the Court notes the plaintiffs have already deposed (and are scheduled to depose) numerous senior-level employees intimately familiar with the design, development, safety, marketing, and distribution of the subject drugs. Def. Letter pp. 6-7. Thus, it seems any information sought from these witnesses has been obtained (or will be obtained) through other deponents and would be duplicative.

Considering the totality of the circumstances – the absence of any indication that these executives possess information that is more than marginally relevant to this litigation, as well as the information's duplicative nature and availability through other deponents – the Court will not compel Mr. Trudeau or Dr. Riemann to appear for the requested depositions.

III. CONCLUSION

The Court will not compel Bayer to product Mr. van der Werff, Mr. Trudeau, or Dr. Riemann for the requested depositions. If plaintiffs have another means of compelling Mr. van der Werff to testify they may pursue those means. However, the time it takes to pursue the deposition of Mr. van der Werff via other

means will not be grounds for a continuance of any deadlines. To the extent that Bayer has access to Mr. van der Werff's custodial files they must be produced.

SO ORDERED

David R. Herndon
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Chief Judge **Date: August 18, 2011**
United States District Court